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INSIGHT EBOOK

OUTSOURCING TRENDS IN MEDICINE

INDUSTRY TRENDS & PAIN POINTS

Featuring Pharma IQ's Top CRO & CMO Shortlists

Outsourcing has been labelled as one of the century's "greatest organizational and industry structure shifts".

Pharma's crutch

The general model in the pharmaceutical and biotechnology industries sees market authorisation holders (MAH) rely heavily on external partners to execute a range of activities including the likes of research, development and manufacturing.

Rising pressure from the public regarding medicine price points compounds the appeal of outsourcing as a route to cool costs and free up internal resource burdens.

But, as pharma continues to wrestle with stagnant innovation levels and high failure rates, despite the boost in funds poured into R&D pipelines, cheaper running costs are no longer the primary goal.

Results Healthcare's 2017 Review of Outsource Manufacturing in Pharma and biotech notes that between 2017 and 2021 a staggering $83bn of pharma sales will be hit due to patent expiries.

R&D

The era of precision medicines will only ask for more efficiency in drug discovery and development. In order to preserve the bottom line, market authorization holders will need to discover medications faster and more efficiently.

In fact the top drivers for respondents in the 2016 NICE insight CDMO Outsourcing survey included improving quality, efficiency and technical/operational expertise. The top reason in 2017 was access to specialized technologies.

Outsourcing provides a cost effective route to access the market's newest and most efficient in vitro, in vivo and in silico methodologies that can better inform drug development.

R&D outsourcing also allows MAHs to access sophisticated technologies such as artificial intelligence and machine learning for quick analysis and testing of vast data sources. Names such as **Pfizer, Lundbeck and Merck** are known to have deployed collaborations to tap into these analytics capabilities.

Read: The Future of Drug Discovery: AI

Biopharma firms are teaming up with academic centres to stimulate the identification of new medical breakthroughs to inspire therapies of the future. Some firms are even venturing to finally entertain open innovation models with peers.

To fast-track the development of innovative medicines, Nashville Biosciences, a wholly owned subsidiary of Vanderbilt University Medical Center (VUMC), is opening access to its extensive genomic and bioinformatics resources. Thanks to the biotech start-up, pharmaceutical, biologics and other life science companies will be able to leverage the wealth of data contained within the medical center's

genomics and health information technology resources.

This access will help accelerate the discovery and development of new treatments for patients, while supporting institutional research efforts.

The Pharma IQ network noted in our recent research that they were most likely to outsource clinical monitoring, project management and pharmacovigilance to a CRO.

Manufacturing

A positive road lies ahead for outsourced manufacturing, Visiongain asserts that outsourcing will grow to become a $43.7 billion dollar industry in the next eight years. **Results Healthcare** forecasts that in the face of innovation struggles, around 220 new drugs will be introduced to the market by 2021, some of which will need to be supported by contract manufacturers.

The advisory firm continues: "With the regulatory pressures of recent years, the choice of suppliers is more constrained, which places suppliers that meet regulatory requirements in a better negotiating position."

Tall compliance hurdles are complicating growth in some areas in biomanufacturing. Injectables are expected to take the largest share of growth in terms of delivery methods. Limited capacity for sterile and aseptic fill production is triggering tranches of funding into the vertical.

Biologics treatments have marked as a key growth area even though traditionally industry preference has been to produce large molecule treatments in-house. Despite the surge of investment into biologics capacities, the

largest section of outsourced manufacturing revolves around small molecule therapies. The technology and production abilities for biologics vastly contrast those for small molecules. The key to success for these providers is to win projects in their early stages as many avoid switching suppliers once clinical trials commence.

Selection

Despite its considerable outsourcing experience, pharma is still trying to find the perfect recipe for the selection stage as even the most rigorous selection process can fail to get things right first time round - with problems being flagged up 12-18 months after entering a partnership.

The majority of the Pharma IQ respondents in our Top CRO and CMO research noted that contract reviews would happen only when an issue came up or on an annual basis.

A few participants clarified that reviews are ongoing as part of their oversight to ensure compliance with contracted services but "not for the purpose of switching CROs, that would only be done in extreme circumstances of failure to perform."

Lack of quality was the aspect voted most likely to end a partnership with a CRO, attracting 65% of the votes. A high level of mistakes was the next option with 12% of the vote.

Performance, Quality and Regulatory Requirements

Drug manufacturers should avoid slipping into the misconception that when they employ a CMO they are also outsourcing the compliance liability attached to the product. The compliance and quality of a CMO must be managed via audits and frequent visits to verify the processes and equipment being deployed.

Cristina Falcão notes that when a company is looking for CRO and CMO partners it should be aware of domestic and foreign regulatory requirements.

Due-diligence auditing will be necessary to thoroughly evaluate the alignment of the two parties for the upcoming technology transfer.

It's important to build in as much supply assurance as possible upfront into agreement terms. Strong quality agreements will be needed between all parties to protect the integrity of the product. Contracts must be written, and the company must conduct quality oversight of all contract manufacturers have a written quality agreement and other documents, to clearly identify the responsibilities of each party.

It is important to have a project team working together on both ends in a proactive manner, targeting dates, batches, and resources.

Overcrowding of contacts

Across its various functions a MAH may work with 350+ external partner contacts, unsurprisingly many in the industry wish to shrink this number. Manufacturers are seeking strategic partnerships so they can maintain a global reach with the technologies they require but via a smaller base of contacts.

Language Obstacles, Cultural Gaps and Time Zones

The preferred outsourcing option is off shoring (the company providing the outsourced services is in a low-cost country far from the country where the recipient of services is located); consequently the language barrier can oftentimes slow down the communication process and lead to potentially dangerous misunderstandings.

Different time zones can be responsible for delays in data transfer and compromised deadlines.

Cultural gaps may be the source of erroneous perceptions, especially if there is not a cross-functional and cross-geographical team involved.

Many pharmaceutical companies that outsource major projects, can end up

managing relationships at arm's length, because distance and lack of visibility of project progress , may foster problems that will take more time to identify; often times the key to a successful outsourcing strategy in off shoring countries, lies in having a company person in place to mitigate business risks.

Consolidation and market movement

Consolidation has not occurred at the pace forecasted, however the substantial rate of mergers and acquisitions can still confuse awareness on a Contract Manufacturing Organization's (CMO) capabilities and sites it can provide access to. Although, the CMO sector is not as consolidated as the Contract Research Organization (CRO) sector, on this note **Results Healthcare** projects that the top 7 CROs capture over 50% of market share.

With the outsourcing trend forecasted to continue, the Pharma IQ network voted on who they ranked as the 10 best Contract Research Organizations and Contract Manufacturing Organizations. Access these below.

View Pharma IQ's Top 10 CMOs

View Pharma IQ's Top 10 CROs